IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS HOUSTON DIVISION

QUALITY INFUSION CARE, INC., §

Plaintiff, §

V. § CIVIL ACTION NO. H-07-1508

BANDANA TRADING, INC., §

Defendant. §

MEMORANDUM OPINION

Pending before the court¹ is Defendant's Motion for Summary Judgment (Docket Entry No. 8). Because the court finds no subject matter jurisdiction, the court **DISMISSES** Plaintiff's action against Defendant under Rule 12(h)(3) of the Federal Rules of Civil Procedure without reaching the merits of Defendant's motion.

I. Case Background

Quality Infusion Care, Inc. ("Plaintiff") brought this action against Progressive Design, Inc. ("Defendant"), alleging a violation of the guidelines and policies of the Food and Drug Administration ("FDA") regarding the allotment of drugs during a shortage.² Plaintiff is a Texas corporation located in Houston,

The parties consented to proceed before the undersigned magistrate judge for all proceedings, including trial and final judgment, pursuant to 28 U.S.C. § 636(c) and Federal Rule of Civil Procedure 73. Docket Entry Nos. 11, 15, 16.

 $[\]frac{2}{2}$ See Plaintiff's Original Complaint ("Complaint"), Docket Entry No. 1, p. 1.

Texas.³ Defendant is a California corporation located in San Luis Obispo, California.⁴

Plaintiff is a licensed pharmacy specializing in home infusion therapy, which involves the administration of medication through intravenous, subcutaneous, and epidural routes. Defendant, doing business as CT International Incorporated, is a distributor of pharmaceutical drugs, including certain blood products. Plaintiff entered into an agreement with Defendant to purchase certain quantities of Gamunex, an immune globulin drug. During the existence of said agreement, Gamunex came under short supply. In March of 2005, Defendant stopped its Gamunex shipments to Plaintiff and demanded payment on outstanding invoices.

On May 24, 2005, Defendant filed a complaint in the Superior Court of the State of California, alleging, inter alia, Plaintiff's failure to make payment under the parties' written agreement. Plaintiff filed a cross-complaint on August 1, 2005, alleging

^{3 &}lt;u>Id.</u>

^{10.} at 2.

⁵ <u>Id.</u>

⁶ Id.

 $[\]frac{7}{10.}$ at 2-3.

^{8 &}lt;u>Id.</u>

Id.; accord Defendant's Motion to Dismiss, Docket Entry No. 8, p. 8.

See Defendant's Motion to Dismiss, Docket Entry No. 8, Ex. A, Complaint for Breach of Contract and Common Counts, p. 6.

breach of the implied covenant of good faith and fair dealing and tortious interference with a prospective financial advantage. ¹¹ In September of 2006, a jury returned a verdict in favor of Defendant on all causes of action. ¹² Plaintiff filed a motion for new trial on December 4, 2006, ¹³ and a notice of appeal on January 8, 2007. ¹⁴

Plaintiff filed this federal action on May 4, 2007 pursuant to the United States Supreme Court's ruling in Cort v. Ash regarding an implied cause of action in federal statutes. 442 U.S. 66, 78 (1975). Plaintiff asserts that Defendant violated FDA drug allocation guidelines during a recognized shortage and seeks actual damages in an undisclosed amount, along with pre-judgment interest, attorneys' fees, and costs. 6 On July 9, 2007, Defendant filed a Motion to Dismiss For Failure to State a Claim Upon Which Relief Can Be Granted (F.R.C.P. 12(B)(6)), asserting that this federal action is barred under the principles of res judicata. In a footnote, Defendant argues that Plaintiff does not have standing to

See id. at Ex. B, Cross-Complaint for Breach of Contract, p. 1.

See id. at Ex. E, Amended Judgment on Special Verdict, p. 1.

See id. at Ex. G, Defendant/Cross-Complainant's Memorandum, p. 1.

See id. at Ex. F, Notice of Appeal, p. 1.

Complaint, Docket Entry No. 1, p. 3.

¹⁶ Id. at 4-5.

Defendant's motion was initially filed as a motion to dismiss, but was converted by this court to a motion for summary judgment based upon Defendant's reliance on exhibits outside Plaintiff's complaint and pursuant to Fed. R. Civ. P. 12(c). See Order dated July 20, 2007, Docket Entry No. 10, p. 1.

bring this lawsuit under <u>Cort v. Ash</u>, but Defendant does not address the issue further therein. Plaintiff did not file a response to Defendant's motion.

II. Analysis

Pursuant to its obligation to examine the basis for the exercise of federal subject matter jurisdiction, <u>Smith v. Texas Children's Hosp.</u>, 172 F.3d 923, 925 (5th Cir. 1999), and its authority to do so <u>sua sponte</u> at any time under Fed. R. Civ. P. 12(h)(3), the court must first determine whether Plaintiff has standing to bring a claim under the Food, Drug, and Cosmetic Act ("FDCA"). See <u>Giles v. NYL Care Health Plans, Inc.</u>, 172 F.3d 332, 336 (5th Cir. 1999).

In <u>Cort v. Ash</u>, a stockholder asserted a derivative claim against a corporation for alleged violations of a criminal statute. 422 U.S. at 68. The stockholder argued that, although it was not explicitly stated, a private cause of action was implied under the statute at issue. <u>Id.</u> The Supreme Court ultimately found that private relief was not available. <u>Id.</u> at 77-78. In making this determination, the Court considered four factors: (1) whether the plaintiff was "one of the class for whose especial benefit the statute was enacted;" (2) whether there was any indication of

See Defendant's Motion to Dismiss, Docket Entry No. 8, p. 1, n. 1.

The FDA, as the designee of the Secretary of Health and Human Services, is granted the authority regulate drugs, among other things, by the FDCA. 21 U.S.C. \S 301 et seq.

legislative intent, explicit or implicit, to create or deny such a remedy; (3) whether the implication of a private remedy was consistent with the "underlying purposes of the legislative scheme;" and (4) whether the cause of action was "one traditionally relegated to state law, in an area basically the concern of the States, so that it would be inappropriate to infer a cause of action based solely on federal law." Id. at 78.

Since its decision in <u>Cort</u>, the Supreme Court has modified the focus of its inquiry when considering whether a federal statute implies a private cause of action. <u>See Transamerica Mortqage Advisors</u>, Inc. v. Lewis, 444 U.S. 11, 15-16 (1979); <u>Touche Ross & Co. v. Redington</u>, 442 U.S. 560, 575-76 (1979); <u>see also Thompson v. Thompson</u>, 484 U.S. 174, 189 (1988) (Scalia, J., concurring) ("[W]e effectively overruled the <u>Cort v. Ash</u> analysis in <u>Touche Ross</u> . . . and <u>Transamerica</u> . . . , converting one of its four factors (congressional intent) into the determinative factor.").

More importantly, regardless of the factor(s) to be considered in implying the right to a private remedy, the Fifth Circuit has specifically recognized that the FDCA does not create a private cause of action. See IQ Prod. Co. v. Pennzoil Prod. Co., 305 F.3d 368, 374 (5th Cir. 2002); see also Hinojosa v. Guidant Corp., No. Civ.A. C-06-159, 2006 WL 903720, at *3 (S.D. Tex. April 7, 2006) ("It is well-settled that the . . . FDCA [does] not provide for a private, federal cause of action."). Other circuits have

explicitly stated that the FDCA does not provide a private right of action and that enforcement is restricted to suits by the United States, and under some circumstances, by a state. See e.g., In re Orthopedic Bone Screw Prod. Liab. Litiq., 193 F.3d 781, 788 (3d Cir. 1999); Mylan Lab., Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993); Kemp v. Medtronic, Inc., 231 F.3d 216, 236 (6th Cir. 2000); Pacific Trading Co. v. Wilson & Co., 547 F.2d 367, 370 (7th Cir. 1976).

Accordingly, the court finds that the FDCA does not provide a cause of action for Plaintiff as a private party suing for civil damages. Under Rule 12(h)(3) of the Federal Rules of Civil Procedure, Plaintiff's allegation regarding violation of FDA guidelines must be dismissed for lack of subject matter jurisdiction.

III. Conclusion

Based on the foregoing, this case is DISMISSED.

SIGNED in Houston, Texas, this 8th day of January, 2008.

Xancy K Johnson United States Magistrate Judge